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Dhanasingh et al.

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(54) **ELECTRODE FOR COMMON CAVITY COCHLEAR MALFORMATION**

(71) Applicant: **MED-EL Elektromedizinische Geraete GmbH**, Innsbruck (AT)

(72) Inventors: **Anandhan Dhanasingh**, Innsbruck (AT); **Claude Jolly**, Innsbruck (AT); **Rocco Calabrese Gac**, Santiago (CL)

(73) Assignee: **MED-EL Elektromedizinische Geraete GmbH**, Innsbruck (AT)

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(51) **Int. Cl.**
A61N 1/05 (2006.01)

(52) **U.S. Cl.**
CPC ***A61N 1/0541*** (2013.01)

(58) **Field of Classification Search**
CPC A61N 1/0541; A61N 1/36032
See application file for complete search history.

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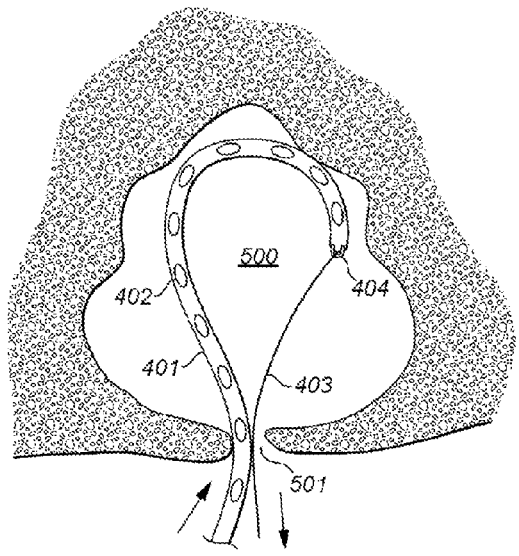
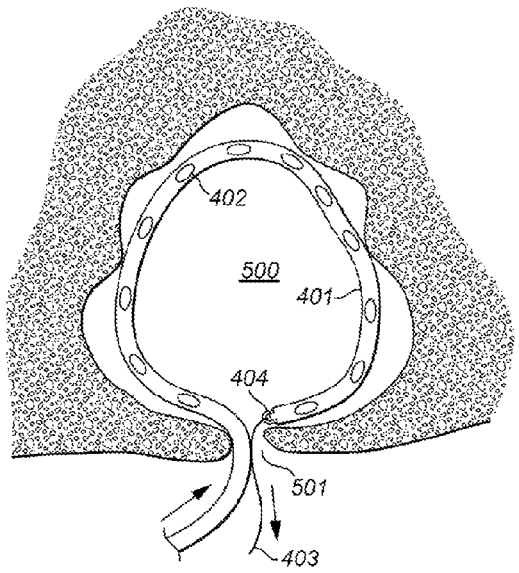
Primary Examiner — Eugene Wu
(74) *Attorney, Agent, or Firm* — Sunstein Kann Murphy & Timbers LLP

(57) **ABSTRACT**

An implantable electrode is described for a cochlear implant patient with a cochlea having a single internal cavity defined by an outer cavity wall. The electrode includes an extra-cochlear electrode lead with signal wires for conducting electrical stimulation signals. An intra-cochlear electrode array is configured to be inserted into the cochlea through a single cochleostomy opening and is made of a resilient carrier material having an outer surface with one or more stimulation contacts for delivering the electrical stimulation signals to adjacent neural tissue. An insertion line is attached to the outer surface of the electrode array at a distal end and is made of a line material different from the electrode carrier material. The insertion line is configured to have an extra-cochlear end extending outside the cochleostomy opening during surgical insertion of the electrode array into the cochlea.

5 Claims, 6 Drawing Sheets





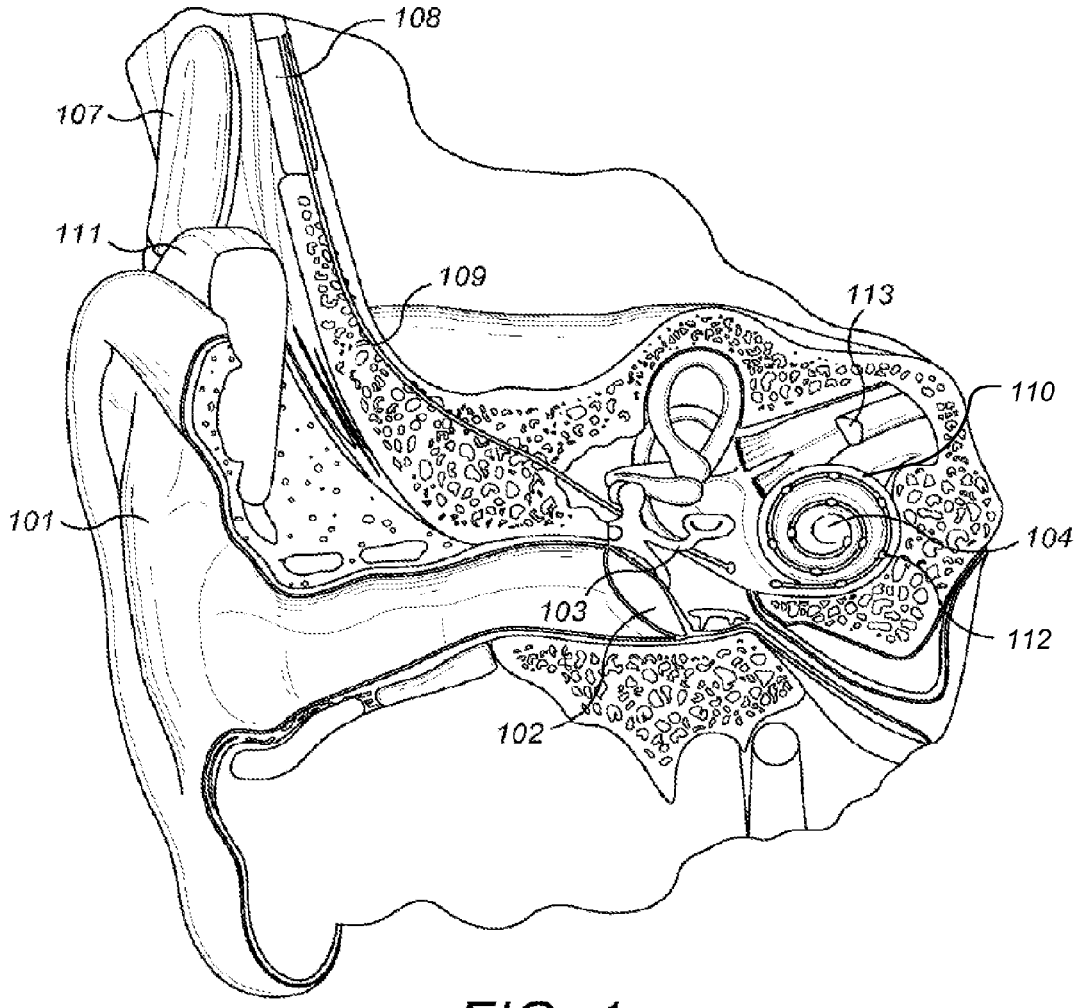


FIG. 1

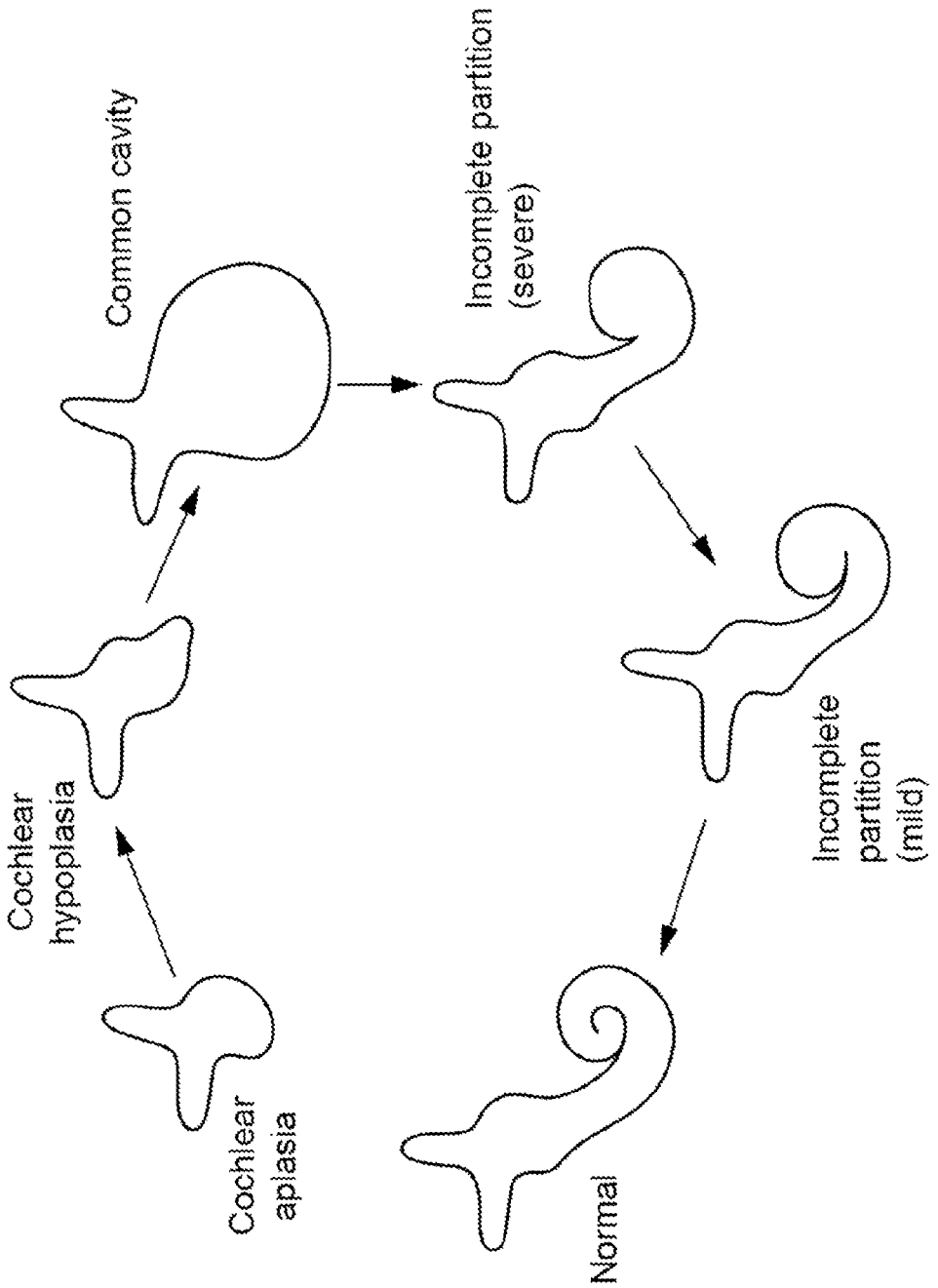

Cochlear aplasia
Cochlear hypoplasia
Common cavity
Incomplete partition (severe)
Incomplete partition (mild)
Normal

FIG. 2

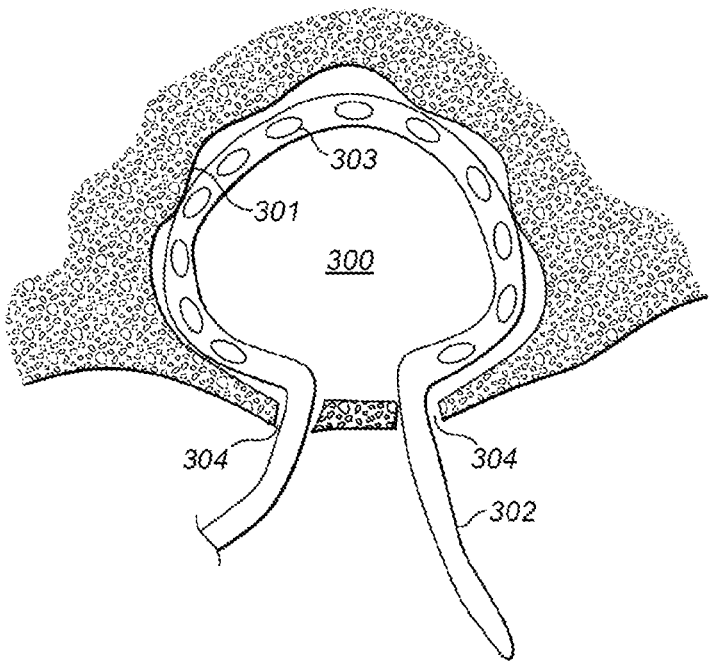


FIG. 3A

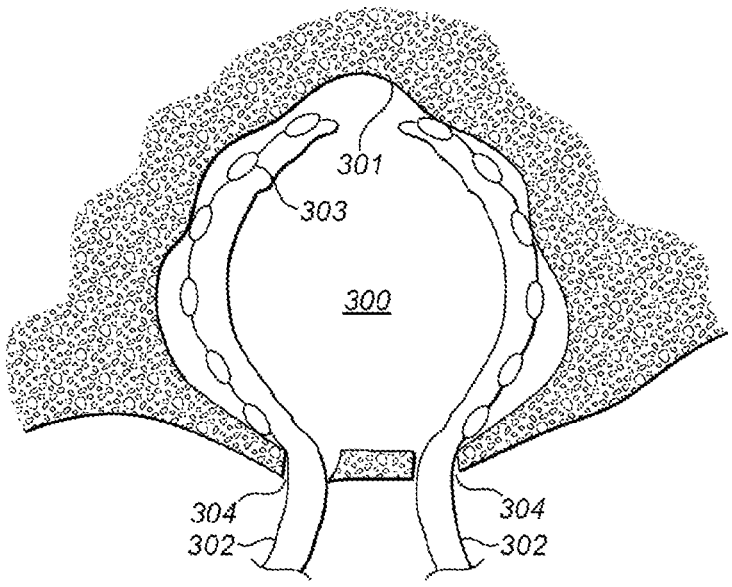


FIG. 3B

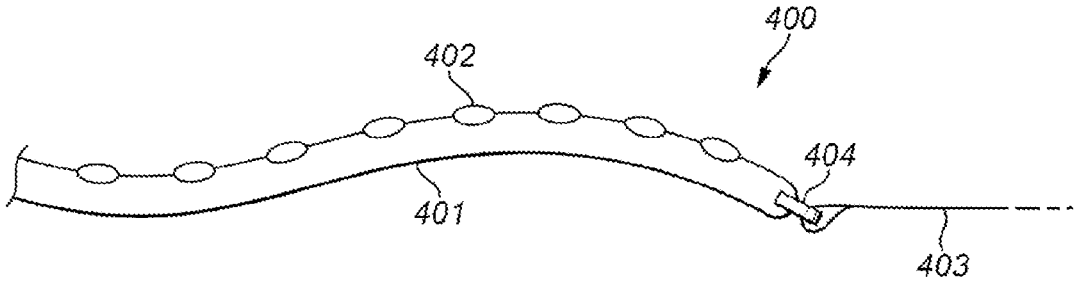


FIG. 4A

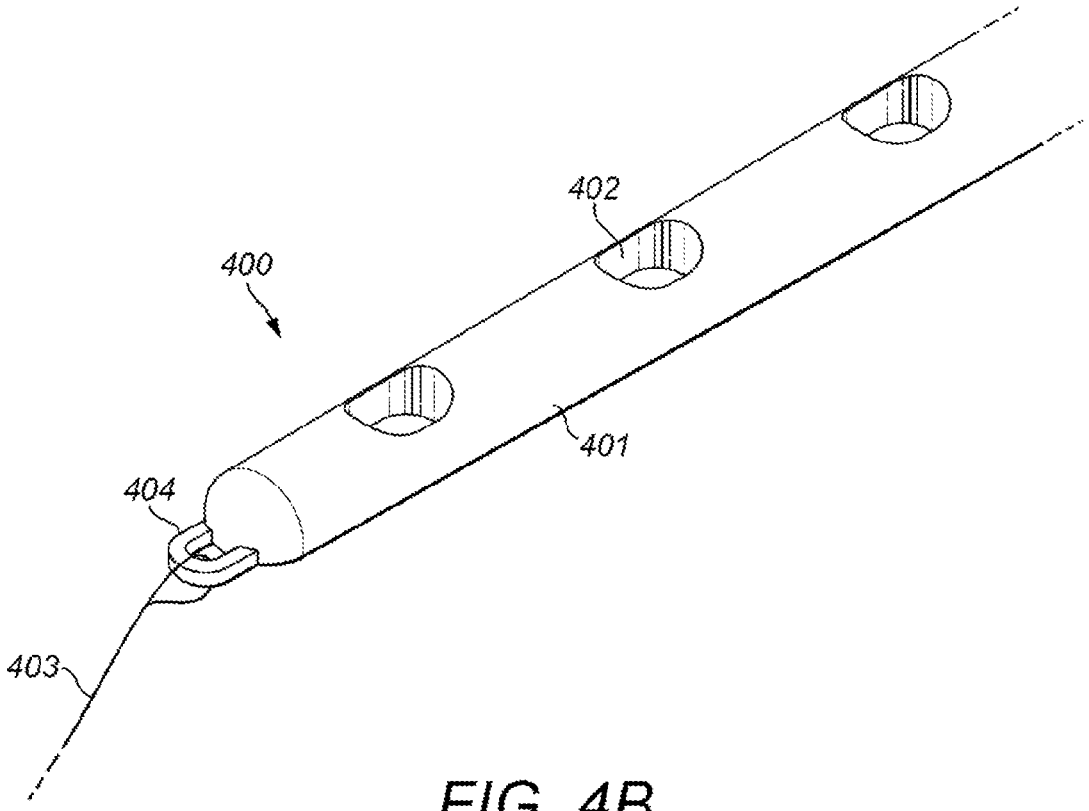


FIG. 4B

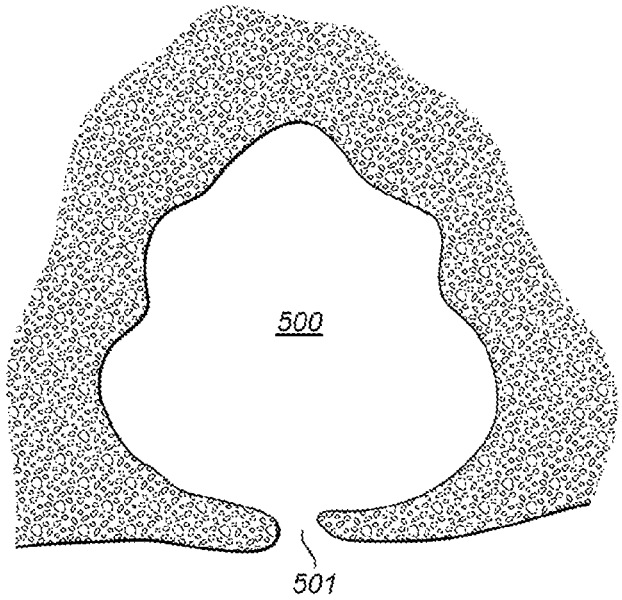


FIG. 5A

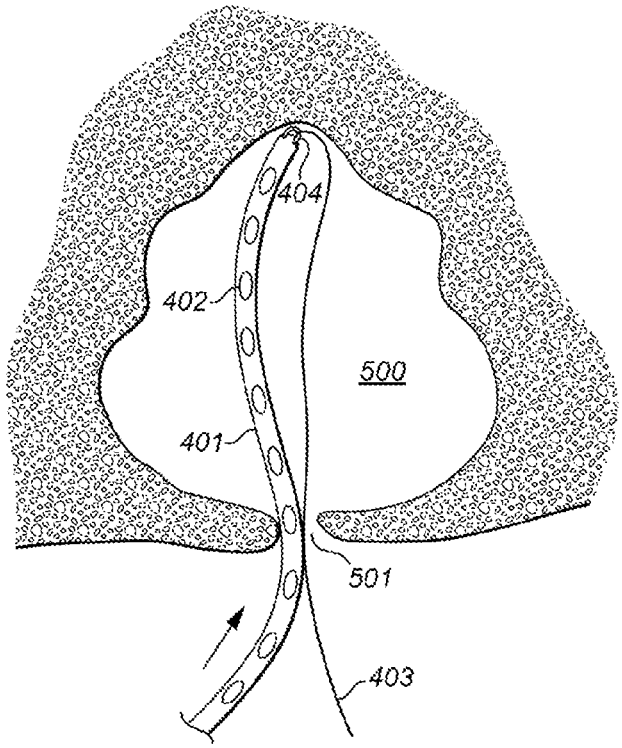


FIG. 5B

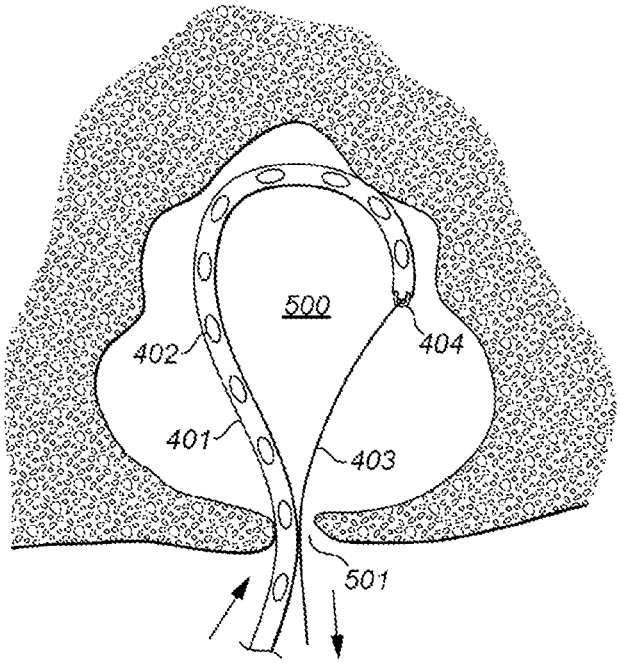


FIG. 5C

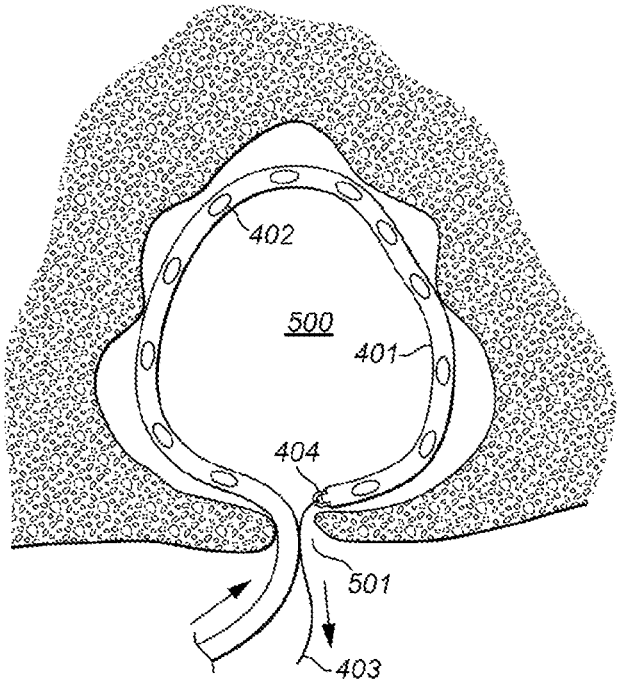


FIG. 5D

ELECTRODE FOR COMMON CAVITY COCHLEAR MALFORMATION

This application is a divisional of U.S. patent application Ser. No. 14/512,156, now U.S. Pat. No. 9,333,338, filed Oct. 10, 2014, which in turn claims priority from U.S. Provisional Patent Application 61/890,927, filed Oct. 15, 2013, both of which are incorporated herein by reference in their entireties.

FIELD OF THE INVENTION

The present invention relates to medical implants, and more specifically to an implantable electrode for use in cochlear implant systems in patients having a malformed cochlea.

BACKGROUND ART

A normal ear transmits sounds as shown in FIG. **1** through the outer ear **101** to the tympanic membrane (eardrum) **102**, which moves the bones of the middle ear **103** (malleus, incus, and stapes), which in turn vibrate the oval window and round window openings of the cochlea **104**. The cochlea **104** is a long narrow duct wound spirally about its axis for approximately two and a half turns. The cochlea **104** includes an upper channel known as the scala vestibuli and a lower channel known as the scala tympani, which are connected by the cochlear duct. The scala tympani forms an upright spiraling cone with a center called the modiolar where the spiral ganglion cells of the acoustic nerve **113** reside. In response to received sounds transmitted by the middle ear **103**, the fluid-filled cochlea **104** functions as a transducer to generate electric pulses that are transmitted to the cochlear nerve **113**, and ultimately to the brain.

Hearing is impaired when there are problems in the ability to transduce external sounds into meaningful action potentials along the neural substrate of the cochlea. In such cases a cochlear implant is an auditory prosthesis which uses an implanted stimulation electrode to bypass the acoustic transducing mechanism of the ear and instead stimulate auditory nerve tissue directly with small currents delivered by multiple electrode contacts distributed along the electrode.

FIG. **1** also shows some components of a typical cochlear implant system which includes an external microphone that provides an audio signal input to an external signal processing stage **111** where various signal processing schemes can be implemented. The processed signal is then converted into a digital data format, such as a sequence of data frames, for transmission into the implant stimulator **108**. Besides extracting the audio information, the implant stimulator **108** also performs additional signal processing such as error correction, pulse formation, etc., and produces a stimulation pattern (based on the extracted audio information) that is sent through connected wires **109** to an implanted electrode carrier **110**. Typically, this electrode carrier **110** includes multiple electrodes on its surface that provide selective stimulation of the cochlea **104**.

In some persons, the cochlear shape fails to develop properly and various malformation conditions can occur such as those shown in FIG. **2**: cochlear aplasia, cochlear hypoplasia, common cavity (CC) malformation, and incomplete partitioning. Specifically in a common cavity malformation the cochlea and the vestibule are represented by a single chamber. This structure may have cochlear and vestibular neural structures, but it completely lacks inter-scala separation (no basilar membrane), no modiolus trunk, and it

appears as a single cavity. The neural structures are believed to be present at the bony capsule defining the outer cavity wall. The specific size of the cavity can vary significantly and can be measured using medical imaging.

Placing an electrode inside a malformed common cavity cochlea is not straightforward and needs utmost care to ensure that the stimulation contacts are either touching or very close to the outer wall of the cavity. The current technique involves making two cochleostomy openings in the outer surface of the cochlea for the electrode placement, which is undesirably traumatic.

FIG. **3**A shows one approach wherein the electrode array **302** has an extended distal end. Two cochleostomies **304** are made in the outer surface of the cochlea **300**, the electrode array **302** is inserted through one of the cochleostomies **304**, and the distal tip of the electrode array **302** is retrieved and pulled through the other cochleostomy **304**. The surgeon has to manipulate the electrode array **302** to attempt to place the stimulation contacts **303** against the outer wall **301** of the cavity, after which the final position of the electrode array **302** is fixed and the distal extension may be removed.

FIG. **3**B shows another approach for electrode implantation in a common cavity, again requiring two cochleostomies **304** in the outer surface of the cochlea **300**. Two separate electrode arrays **302** are used, one through each cochleostomy **304**, and again considerable surgical skill is needed to manipulate the electrode arrays **302** to place their stimulation contacts **303** adjacent to the outer wall **301** of the cavity. Both techniques are highly traumatic in requiring two cochleostomies and both require considerable surgical skill to be effective.

SUMMARY OF THE INVENTION

Embodiments of the present invention are directed to a method of implanting a cochlear implant electrode into a cochlea having a single internal cavity defined by an outer cavity wall (e.g., a malformed common cavity cochlea). An implantable electrode array is made of a resilient electrode carrier material and has an outer surface with one or more stimulation contacts for delivering the electrical stimulation signals to adjacent neural tissue. A distal end of the electrode array is attached to an insertion line made of a line material different from the electrode carrier material. The distal end of the electrode array is inserted through a single cochleostomy opening into the cochlea while an extra-cochlear end of the insertion line is held outside the cochleostomy opening. The remainder of the electrode array is inserted through the cochleostomy opening into the cochlea while continuing to hold the extra-cochlear end outside the cochlea to maneuver all of the stimulation contacts against the outer cavity wall.

The insertion line may be configured to be cut after feeding the electrode array into the cochlea so that no part of the insertion line remains within the cochleostomy opening. The electrode array may be fed through the cochleostomy opening until the distal end of the electrode array contacts the outer cavity wall opposite the cochleostomy opening. Then after the distal end of the electrode array contacts the outer cavity wall, the insertion line may be retracted back through the cochleostomy opening while continuing to feed the electrode array through the cochleostomy opening until the distal end of the electrode array reaches the cochleostomy opening. The distal end of the electrode array may include an attachment ring to which the insertion line is attached. The line material may be a medical grade suture material.

Embodiments of the present invention also include a corresponding implantable electrode. An extra-cochlear electrode lead contains signal wires for conducting electrical stimulation signals. An intra-cochlear electrode array is configured to be inserted into the cochlea through a single cochleostomy opening and is made of a resilient carrier material having an outer surface with one or more stimulation contacts for delivering the electrical stimulation signals to adjacent neural tissue. An insertion line is attached to the outer surface of the electrode array at a distal end and is made of a line material different from the electrode carrier material. The insertion line is configured to have an extra-cochlear end extending outside the cochleostomy opening during surgical insertion of the electrode array into the cochlea.

In specific embodiments, the insertion line may be configured to be cut after feeding the electrode array into the cochlea so that no part of the insertion line remains within the cochleostomy opening. The distal end of the electrode array may include an attachment ring to which the insertion line is attached. The line material may be a medical grade suture material. Embodiments of the present invention also include a complete cochlear implant system having an electrode array according to any of the above.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** shows elements of a human ear having a typical cochlear implant system.

FIG. **2** illustrates various cochlear malformation shapes.

FIG. **3** A-B show conventional electrode insertion into a common cavity cochlea using two cochleostomies.

FIG. **4** A-B show a common cavity electrode having an insertion line according to an embodiment of the present invention.

FIG. **5** A-D shows insertion of a common cavity electrode into a malformed common cavity cochlea.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

Various embodiments of the present invention are directed to an implantable electrode for a common cavity cochlea having an insertion line at a distal end of the electrode array that is suitable for insertion into a malformed common cavity cochlea through a single cochleostomy opening. Because the electrode is configured for insertion through a single cochleostomy opening rather than requiring two cochleostomies as in existing conventional arrangements, the amount of trauma to the cochlea is reduced and an easier surgical insertion process can be used. And, the insertion line approach is suitable for using a conventional cochlear implant electrode without significant structural alteration or without special fabrication specifically for a common cavity cochlea.

FIG. **4** A-B show an implantable common cavity electrode **400** according to one specific embodiment of the present invention. An extra-cochlear electrode lead (not shown) contains signal wires for conducting electrical stimulation signals to an intra-cochlear electrode array **401** made of a resilient carrier material (e.g., medical grade silicone). The outer surface of the electrode array **401** has one or more stimulation contacts **402** for delivering the electrical stimulation signals to adjacent neural tissue in the outer cavity wall of a malformed common cavity cochlea. The electrode array **401** is configured to be inserted into the cochlea through a single cochleostomy opening, thereby creating far less trauma and using a far simpler surgical technique.

An insertion line **403** is attached to the outer surface of the electrode array **401** at a distal end, for example, by fixation to an attachment ring **404**. The insertion line **403** is made of a line material different from the electrode carrier material; for example, medical grade surgical suture material. The insertion line **403** is long enough to have an extra-cochlear end that extends outside the cochleostomy opening during surgical insertion of the electrode array **401** into the cochlea, which is therefore well-suited to be fixedly held by the surgeon during the insertion process.

FIG. **5** A shows a malformed cochlea having a single internal cavity **500** defined by an outer cavity wall (e.g., a malformed common cavity cochlea) having a single cochleostomy opening **501** for insertion of such an electrode array. The distal end of the electrode array **401** initially is inserted through the cochleostomy opening **501** into the internal cavity **500** of the cochlea while an extra-cochlear end of the insertion line **403** is securely held outside the cochleostomy opening **501**. The electrode array **401** is fed through the cochleostomy opening **401** until the distal end of the electrode array **401** contacts the outer cavity wall of the internal cavity **500** opposite the cochleostomy opening **501**, as shown in FIG. **5**B. Then after the distal end of the electrode array **401** contacts the outer cavity wall, the insertion line **403** is retracted back through the cochleostomy opening **501** while continuing to feed the electrode array **401** through the cochleostomy opening **501** and while continuing to hold the extra-cochlear end of the insertion line **403** outside the cochlea. As the distal end of the electrode array **401** reaches the cochleostomy opening **501**, as shown in FIG. **5**D, the surgeon maneuvers all of the stimulation contacts **402** against the outer cavity wall of the internal cavity **500**.

The specific lengths of the electrode array **401** and/or the insertion line **403** may differ in specific embodiments in order to accommodate different size internal cavities **500**. And the insertion line **403** may be configured to be cut after fully feeding the electrode array **401** into the internal cavity **500** of the cochlea so that no part of the insertion line **403** remains within the cochleostomy opening **501** to avoid bacterial infection.

Although various exemplary embodiments of the invention have been disclosed, it should be apparent to those skilled in the art that various changes and modifications can be made which will achieve some of the advantages of the invention without departing from the true scope of the invention.

What is claimed is:

1. An implantable electrode for a cochlear implant patient with a cochlea having a single internal cavity defined by an outer cavity wall, the electrode comprising:

an extra-cochlear electrode lead containing a plurality of signal wires for conducting electrical stimulation signals;

an intra-cochlear electrode array configured to be inserted into the cochlea through a single cochleostomy opening and made of a resilient carrier material having a distal end and an outer surface with one or more stimulation contacts for delivering the electrical stimulation signals to adjacent neural tissue; and

an insertion line attached to the outer surface of the electrode array at the distal end, and made of a line material different from the electrode carrier material, wherein the insertion line is configured to have an

extra-cochlear end extending outside the cochleostomy opening during surgical insertion of the electrode array into the cochlea;

wherein the electrode array is configured to promote the distal end of the electrode array within the cochlea being retracted back towards the single cochleostomy opening by the insertion line as the electrode array is inserted into the cochlea so as to maneuver the one or more stimulation contacts against an outer cavity wall of the cochlea.

2. The implantable electrode according to claim **1**, wherein the insertion line is configured to be cut after feeding the electrode array into the cochlea so that no part of the insertion line remains within the cochleostomy opening.

3. The implantable electrode according to claim **1**, wherein the distal end of the electrode array includes an attachment ring to which the insertion line is attached.

4. The implantable electrode according to claim **1**, wherein the line material is a medical grade suture material.

5. A cochlear implant system

an implantable electrode according to any of claim **1**; and

an implantable stimulator configured for producing the electrical stimulation signals for delivery by the one more stimulation contacts.

* * * * *